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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,298	SHARPE ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9 and 21-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-9, and 21-38* is/are rejected.

7)☒ Claim(s) *1, 21, 30, and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5, 7-9 and 21-38 are pending. Applicants previously cancelled claims 10-20. Applicants have newly cancelled claim 6. Claim 38 is new. Applicants have amended claims 1 and 21. Receipt and consideration of Applicants' amended claim set and arguments/remarks filed on August 29, 2008 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 29, 2008 has been entered.

Claim Objections

Claims 1, 21, 30, and 38 are objected to because of the following informalities: the words "present in" should be inserted between the words "is an" on line 4 of said claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' specification does not provide support for compositions that are free of lactose. Applicants' specification provides support for the general concept that the compositions are free of a bulking agent or carrier, but no specific bulking agents are mentioned. It is also noted that there is no mention of lactose within the four corners of Applicants' specification and Applicants have not indicated where support for compositions free of lactose can be found in their specification.

The remaining claims are rejected for depending upon a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9, 28-29, and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-9, 28-29, and 36-37 are indefinite because these claims recite a particle size range of "less than about 4.7 microns." The phrase "less than about" is indefinite, because it simultaneously claims two different ranges. An ordinary skilled artisan would

be unable to ascertain whether the required particle size is less than 4.7 microns or about 4.7 microns. The required maximum particle size is also rendered indefinite, because "less than" is a static range, whereas about is a dynamic range, and the ordinary skilled artisan would be unable to ascertain the metes and bounds of the recited particle size. Appropriate correction is required.

Claim 8 recites the limitation "the percent of fine particles dispensed" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the percent of fine particles dispensed" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "the percent of fine particles dispensed" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "the percent of fine particles dispensed" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitation "the percent of fine particles dispensed" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites the limitation "the percent of fine particles dispensed" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 21, 26, 28-30, and 36-37 under 35 U.S.C. 102(b) as being anticipated by Fassberg (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record, which have been restated below for Applicants' convenience.

Applicants claim a metered dose inhaler containing an aerosol suspension formulation comprising an effective amount of mometasone furoate, a dry powder surfactant, and HFA 227, wherein the surfactant is presenting an amount of 0.002 to 0.01% by weight.

In Example XXIII (col. 8, lines 53-56), for example, Fassberg exemplifies a composition consisting of **0.1% w/w mometasone furoate, 0.01% w/w TWEEN 20 (i.e. a surfactant), and 99.89% w/w of HFC 227 (i.e. HFA 227)**. The rejected claims do not require any specific surfactant.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the instant claims are in condition for allowance. This is not a substantive argument, and is found unpersuasive for the reasons stated above. The instant rejection remains proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-5, 7-9 and 21-37 under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759) **is maintained** for the reasons of record restated below and amended to reflect Applicants claim amendments. Claim 38 is appended to this rejection for the reasons of record. In summary, **claims 1-5, 7-9, and 21-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fassberg et al. (U.S. Patent No. 5,474,759).**

Applicant Claims

Applicants claim (1) a metered dose inhaler containing an aerosol suspension formulation consisting of (a) an effective amount of mometasone furoate, (b) a dry powder surfactant, and (c) HFA 227, wherein the surfactant is presenting an amount of 0.002 to 0.01% by weight, and the surfactant is selected from the group consisting of lecithin, stearic acid, palmitic acid, magnesium stearate, magnesium palmitate, and magnesium laureate; and (2) a MDI as described above, wherein the composition comprises components (a)-(c) described above and is free of lactose.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Fassberg discloses suspension aerosol formulations in, for example, in claim 10 which discloses formulations comprising **0.01-1% w/w mometasone furoate, 25-99.99% HFC 227 (i.e. 1,1,1,2,3,3,3-heptafluoropropane), 0-75% excipient, and 0-3% surfactant**. Fassberg describes the invented formulations as being directed to compositions that are substantially free of CFC's and are particularly **useful in metered dose-pressurized inhalators** (i.e. MDIs) (col. 1, lines 15-20). The suspensions are made by preferably **pressure filling or cold filling procedures into aerosol containers** (e.g. MDIs) (col. 6, line 66 through col. 7, line 3). It is noted that soya lecithin is identified by Fassberg as a preferred surfactant (col. 5, lines 49-50). Soya lecithin reads on lecithin. The amount of mometasone furoate disclosed by Fassberg and expressed in units of weight percent is assumed to correspond to or overlap with the amounts of mometasone furoate explicitly recited in Applicants' claims. This is reasonable assumption, as

evidenced by Table 2 on page 12 of Applicants' specification, wherein Applicants disclose MDI compositions comprising 0.1% w/w mometasone furoate.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Fassberg does not anticipate the rejected claims because Fassberg does not explicitly disclose or exemplify compositions comprising surfactant in an amount ranging from 0.002-0.01% w/w, wherein the surfactant is selected from the group consisting of lecithin, stearic acid, palmitic acid, magnesium stearate, magnesium palmitate, and magnesium laureate. This deficiency is nonetheless rendered obvious by the teachings of Fassberg.

Finding of Prima Facie Obviousness Rationale and Motivation ***(MPEP §2142-2143)***

It would have been prima facie obvious to utilize soya lecithin as the surfactant in Fassberg's formulations in any amount from 0-3% by weight, because Fassberg teaches that the invented compositions may comprise surfactant in an amount from 0-3% and that soya lecithin is a preferred surfactant. Regarding the narrower range of surfactant of 0.002-0.01% w/w recited in Applicants claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results

from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. It is noted that Applicants' specification does not contain any data that would lead one to conclude that the instantly claimed range of surfactant imparts any unexpected or surprising property. Applicants' specification makes no allegations of unexpected or surprising results.

Regarding the amount of mometasone furoate recited in several of Applicants' claims, it is assumed that the amount of mometasone furoate disclosed by Fassberg and expressed in units of weight percent corresponds to or overlaps with the amounts of mometasone furoate explicitly recited in Applicants' claims. This is reasonable assumption, as evidenced by Table 2 on page 12 of Applicants' specification, wherein Applicants disclose MDI compositions comprising 0.1% w/w mometasone furoate.

Regarding the recited percent of fine particles and particle size, it is the Examiner's position that the formulations disclosed by Fassberg are necessarily contained within a metered dose inhaler in view of Fassberg's complete disclosure, because it is known that aerosol containers include MDIs. It is impossible to formulate pharmaceutical compositions comprising HFC's without using pressurized containers, because under ambient temperature (i.e. ~25 degrees C) and pressure (i.e. ~1 atmosphere) HFC's are gases, whereas in pressurized containers HFC's a liquids. Regarding claims 8-9 and 36-37, it is the Examiner's position that the emitted efficiency and particle size are necessarily present in the formulations disclosed by Fassberg upon actuation from any MDI. As noted above, claims 8-9 and 36-37 do not specify which aspect of the claimed invention (i.e. the MDI, composition, or both) is responsible for yielding the claimed percent emitted particles and particle size. It is also noted that Fassberg discloses that the

particles of the disclosed formulation have a particle size of 1-5 microns (col. 6, lines 25-26) and the value of "about 4.7 microns" reads on a value of 5 microns. Applicants are reminded that exemplified embodiments are not limiting with regards to the disclosures of a reference. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the instant claims are in condition for allowance. This is not a substantive argument, and is found unpersuasive for the reasons stated above. The instant rejection remains proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-9, and 21-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,474,759 in view of Fassberg (U.S. Patent No. 5,474,759) ("Fassberg").

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in the scope of the aerosol formulations contained within the MDIs of the instant invention and the dependent claims have the same or obvious similar limitations. Independent claim 1 of the instant application is drawn to metered dose inhalers containing a composition **comprising** an aerosol suspension formulation **comprising** mometasone furoate, a surfactant, and HFA 227, also known as 1,1,1,2,3,3,3-heptafluoropropane. Independent claims 1, 8, and 9 of U.S. Patent No. 5,474,759 (USPN '759) are drawn o aerosol formulations consisting essentially of a medicament, including **mometasone furoate** (claims 8 and 9), **HFA 227**, optionally excipients and/or **surfactants**. Mometasone furoate is a medicament. It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to place an aerosol formulation within a metered dose inhaler (MDI), because it is well known in the art to administer aerosol formulations using inhalers, especially MDIs. Therefore, a skilled artisan would have been motivated to make said MDIs containing the aerosol formulations of U.S.P.N. '759 and would have had a reasonable expectation of successfully obtaining MDIs containing said formulations.

Regarding the limitations of claims 2-5, 22-25, and 31-34 of the instant application, these are met by claims 4-7 of USPN '759. The amount of mometasone furoate claimed in USPN '759 and expressed in units of weight percent is assumed to correspond to or overlap with the amounts of mometasone furoate explicitly recited in

Applicants' claims. This is reasonable assumption, as evidenced by Table 2 on page 12 of Applicants' specification, wherein Applicants disclose MDI compositions comprising 0.1% w/w mometasone furoate. Further, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Regarding the new limitations specifying the amount of surfactant present in said claims, the amount of surfactant recited in claims 10-12 overlap with the amount of surfactant recited in Applicants' claims. Further, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Regarding the specific surfactants, it is noted that Fassberg indicates that soya lecithin is a preferred surfactant. Thus, it would have bee prima facie obvious to utilize lecithin as a surfactant in the formulations of

USPN '759 and obtain the instantly claimed MDI's, because Fassberg's formulations are the same formulations claimed in USPN '759.

Regarding the recited percent of fine particles and particle size (i.e. claims 8-9, 28-29, and 36-37) it is the Examiner's position that the emitted efficiency and particle size are necessarily present in the formulations claimed by USPN '759 upon actuation from any MDI. As noted above, claims 8-9 and 36-37 do not specify which aspect of the claimed invention (i.e. the MDI, composition, or both) is responsible for yielding the claimed percent emitted particles and particle size. It is also noted that claim 7 of USPN '759 specifics that the particle size is 1-5 microns, which reads on the recited range of "less than about 4.7 microns." Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-5, 7-9, and 21-38 *prima facie* obvious over claims 1-13 of USPN '759 in view of Fassberg.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the instant claims are in condition for allowance. This is not a substantive argument, and is found unpersuasive for the reasons stated above. The instant rejection remains proper.

Claims 21-38 are provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 20-26 of copending Application No. 11/071,078 (copending '078) in view of García-Marcos et al.

(already of record see 892 accompanying the office action mailed 6/29/06), Berry et al. (U.S. Patent No. 6,068,832) and Fassberg (U.S. Patent No. 5,474,759).

Both the claims of the instant application and copending '078 claim suspension formulations comprising HFA 227 (1,1,1,2,3,3,3-heptafluoropropane) and mometasone furoate as the active agent, as well as metered dose inhalers containing said formulation. The differences between the instant application and copending '078 are that (1) copending '078 recites compositions also compromising formoterol fumarate; (2) the claims of copending '078 do not explicitly recite the presence of surfactants, and (3) no amount of surfactants are recited either in the claims of copending '078. It is noted that Applicants' rejected claims do not prohibit the presence of additional active ingredients and that these claims utilize "comprising" language to describe the aerosol formulation contained within the claimed metered dose inhaler (MDI). Deficiency (1) is cured by the teachings of García-Marcos. García-Marcos teaches that the combination of an anti-inflammatory steroid (e.g. mometasone furoate or budesonide) with a long-acting bronchodilator, such as formoterol furoate is known (see pages 26-28). Furoate is a known ester derivative of formoterol.

Deficiencies (2)-(3) are rendered obvious by the teachings of Berry and Fassberg. Specifically, Berry teaches that surfactant can be used in suspension aerosol formulations to stabilize the contents of these formulations (col. 3, line 55 through col. 44, line 14) and that the amount of surfactant, if present, will be minimized to the lowest concentrations that yield the desired effects (col. 3, line 55 through col. 44, line 14). Berry also teaches that soya lecithin is a possible suitable surfactant. Fassberg teaches compositions similar to those taught by Berry, claimed in copending '078, and claimed by Applicants, and

teaches that soya lecithin is a preferred surfactant. Thus, an ordinary skilled artisan would have been motivated to modify the compositions of copending '078 to comprise surfactant, preferably soya lecithin.

Regarding the amount of surfactant and/or drug present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, claims 21-38 would have been found prima facie obvious over claims 1-9 and 20-26 of copending Application No. 11/071,078 (copending '078) in view of García-Marcos et al. (already of record see 892 accompanying the office action mailed 6/29/06), Berry et al. (U.S. Patent No. 6,068,832) and Fassberg (U.S. Patent No. 5,474,759).

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the instant claims are in condition for allowance. This is not a substantive argument, and is found unpersuasive for the reasons stated above. The instant rejection remains proper.

Claims 21-26, 30-35, and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20, 22-23, and 29 of copending Application No. 11/948,688 (copending '688) in view of Berry et al. (U.S. Patent No. 6,068,832) and Fassberg (U.S. Patent No. 5,474,759).

Independent claim 21 of the instant application claims a metered dose inhaler (MDI) containing an aerosol suspension composition comprising (i) an effective amount of mometasone furoate, (b) a dry powder surfactant, and (c) HFA 227, wherein the surfactant is present in an amount from about 0.002 to about 0.01%. Dependent claim 19 of copending '688 claims a MDI produced by a process that deposits a composition comprising (a) at least one drug and (b) HFA 227. Dependent claim 20 of copending '688 indicates that the MDI composition further comprises at least one excipient selected from a group consisting of cosolvents, surfactants, and propellants. Dependent claim 21 of copending '688 specifies that the drug is selected from at least one of mometasone furoate and formoterol fumarate. Dependent claim 29 of copending '688 claims a MDI produced by a process that deposits a composition comprising (a) mometasone furoate anhydrous, (b) formoterol fumarate, (c) surfactant, and (d) HFA 227.

The difference between the cited claims of the instant application and copending '688 is that the claims of copending '688 do not recite specific surfactants or specific amounts of surfactant or drug. This deficiency is rendered obvious by the teachings of Berry and Fassberg. Specifically, Berry teaches that surfactant can be used in suspension aerosol formulations to stabilize the contents of these formulations (col. 3, line 55 through col. 44, line 14) and that the amount of surfactant, if present, will be minimized

to the lowest concentrations that yield the desired effects (col. 3, line 55 through col. 44, line 14). Berry also teaches that soya lecithin is a possible suitable surfactant. Fassberg teaches compositions similar to those taught by Berry and claimed by Applicants, and teaches that soya lecithin is a preferred surfactant. Thus, an ordinary skilled artisan would have been motivated to modify the compositions of copending to comprise surfactant, and preferably soya lecithin.

Regarding the amount of surfactant and/or drug present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, claims 21-26, 30-35, and 38 would have been found prima facie obvious over claims 19-20, 22-23, and 29 of copending application 11/948,688.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the instant claims are in condition for allowance. This is not a substantive argument, and is found unpersuasive for the reasons stated above. The instant rejection remains proper.

Claims 21-26, 30-35, and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-14 and 24-26 of copending Application No. 11/940,046 ("copending '046") in view of Berry et al. (U.S. Patent No. 6,068,832) and Fassberg (U.S. Patent No. 5,474,759).

Independent claim 21 of the instant application has been described above in the instant office action. Independent claim 13 of copending '046 claims a MDI containing a suspension aerosol composition comprising (a) an effective amount of a compound selected from a group of 4 compounds, including mometasone furoate, mometasone furoate monohydrate, and combinations thereof, (b) HFA 227, and (c) ethanol, wherein the formulation contains less than 500 micrograms of non-volatile residue. Independent claim 24 of copending '046 claims a MDI as described in claim 13 of copending '046, wherein the valve of the MDI comprises less than about 100 micrograms of lubricant.

The difference between the cited claims of the instant application and copending '046 is that the claims of copending '046 do not recite specific surfactants or specific amounts of surfactant or drug. This deficiency is rendered obvious by the teachings of Berry and Fassberg. Specifically, Berry teaches that surfactant can be used in suspension aerosol formulations to stabilize the contents of these formulations (col. 3, line 55 through col. 44, line 14) and that the amount of surfactant, if present, will be minimized to the lowest concentrations that yield the desired effects (col. 3, line 55 through col. 44, line 14). Berry also teaches that soya lecithin is a possible suitable surfactant. Fassberg teaches compositions similar to those taught by Berry and claimed by Applicants, and teaches that soya lecithin is a preferred surfactant. Thus, an ordinary skilled artisan

would have been motivated to modify the compositions of copending to comprise surfactant, and preferably soya lecithin.

Regarding the amount of surfactant and/or drug present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Regarding the amount of non-volatile residue, the claims of the instant application do not recite the presence of any non-volatile residue and the limitation recited in copending '688 reads a zero amount of non-volatile residue. Therefore, claims 21-26, 30-35, and 38 would have been found prima facie obvious over claims 13-14 and 24-26 of copending application 11/940,046.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the instant claims are in condition for allowance. This is not a substantive argument, and is found unpersuasive for the reasons stated above. The instant rejection remains proper.

Claims 21-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 16 of copending Application No. 12/028,853 (copending '853) in view of Berry et al. (U.S. Patent No. 6,068,832) and Fassberg (U.S. Patent No. 5,474,759).

Independent claim 21 of the instant application claims a metered dose inhaler (MDI) containing an aerosol suspension composition comprising (i) an effective amount of mometasone furoate, (b) a dry powder surfactant, and (c) HFA 227, wherein the surfactant is present in an amount from about 0.002 to about 0.01%. Dependent claim 19 of copending '688 claims a MDI produced by a process that deposits a composition comprising (a) at least one drug and (b) HFA 227. Dependent claim 20 of copending '688 indicates that the MDI composition further comprises at least one excipient selected from a group consisting of cosolvents, surfactants, and propellants. Dependent claim 21 of copending '688 specifies that the drug is selected from at least one of mometasone furoate and formoterol fumarate. Dependent claim 29 of copending '688 claims a MDI produced by a process that deposits a composition comprising (a) mometasone furoate anhydrous, (b) formoterol fumarate, (c) surfactant, and (d) HFA 227.

The difference between the cited claims of the instant application and copending '688 is that the claims of copending '688 do not recite specific surfactants, specific amounts of surfactant and drug, or specify the medicament particle size or the fine particle percentage upon actuation of a MDI. These deficiencies are rendered obvious by the teachings of Berry and Fassberg. Specifically, Berry teaches that surfactant can be used in suspension aerosol formulations to stabilize the contents of these formulations (col. 3, line 55 through col. 44, line 14) and that the amount of surfactant, if present, will

be minimized to the lowest concentrations that yield the desired effects (col. 3, line 55 through col. 44, line 14). Berry also teaches that soya lecithin is a possible suitable surfactant. Fassberg teaches compositions similar to those taught by Berry and claimed by Applicants, and teaches that soya lecithin is a preferred surfactant. Thus, an ordinary skilled artisan would have been motivated to modify the compositions of copending to comprise surfactant, and preferably soya lecithin.

Regarding the amount of surfactant and/or drug present in said claims, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Furthermore, concerning the amount of mometasone furoate, Fassberg teaches compositions wherein the effective amount of mometasone furoate ranges from 0.01-1% (e.g. Fassberg's claim 10) expressed in units of weight percent. It is assumed that the prior art teaching for an effective amount of mometasone furoate corresponds to or overlaps with the amounts of mometasone furoate explicitly recited in Applicants' claims. This is reasonable assumption, as evidenced by Table 2 on page 12 of Applicants' specification, wherein Applicants disclose MDI compositions comprising 0.1% w/w mometasone furoate.

Regarding particle size, the prior art teaches that pharmaceutical aerosol suspension formulations have particle sizes of 1-5 microns (e.g. Fassberg's claim 7). Furthermore, it is the Examiner's position that the percent fine particles recited in Applicants' claims would necessarily be present upon actuation of the drug product comprising a MDI as claimed in copending '853, because the formulations contained in the claimed MDI of the instant application and the claimed drug product of copending '853 comprise the same active agent, may comprise the same propellant, and based on the prior art teachings would reasonably be modified to comprise similar amounts of surfactant and soya lecithin surfactant. Furthermore, as noted above, claims 8-9 and 36-37 do not specify which aspect of the claimed invention (i.e. the MDI, composition, or both) is responsible for yielding the claimed percent emitted fine particles and particle size. Therefore, claims 21-26, 30-35, and 38 would have been found prima facie obvious over claims 19-20, 22-23, and 29 of copending application 11/948,688.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Claims 1-5, 7-9 and 21-38 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~9:00-5:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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